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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/485,320 02/08/00 UCHIYAMA

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| EXAMINER |
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HM22/0629

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| MARX, I | |
| ART UNIT | PAPER NUMBER |

1651

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/485,320

Applicant(s)

Uchiyama et al.

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-12 drawn to first product, a composition comprising daidzein and a microorganism, classified in Class 514, subclass 546, for example.

II. Claim 13 drawn to a first method, a method for prevention and treatment of unidentified clinical syndrome or menopausal syndrome by administering a composition comprising a microorganism and daidzein, classified in 424, subclass 95.4, for example.

III. Claim 14 and 28-31 drawn to a second method, the use of a microorganism to make equol and/or a composition for prevention and treatment of unidentified clinical syndrome or menopausal syndrome, classified in Class 435, subclass 119, for example.

IV. Claims 15-26 drawn to second product, a composition comprising equol, classified in Class 514, subclass 183, for example.

V. Claim 32 drawn to a third product, a strain of microorganisms capable of making equol classified in Class 435, subclass 252.1, for example.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

First, the inventions do not match a permitted category as PCT Rule 13.2 does not provide for multiple methods or products in one category.

Second, the products and methods of group I do not share a special technical feature with the products and methods of groups II-V because the nature and properties of each of these products and processes are different, independent and distinct.

A common inventive concept is lacking between groups I and II-V in view of Chang *et al.*, J. of Natural Products, Vol. 58, pages 1892-1896, 1995, which adequately demonstrates that compositions comprising a daidzein-containing substance and microorganisms capable of

metabolizing daidzein lack novelty. See, e.g. page 1892, col. 1. Therefore, the compositions, methods of making and methods of use lack those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

Third, the products of group I do not share a special technical feature with the products of claims IV and V. A composition comprising daidzein/microorganism, a composition comprising equol, and bacterial strains do not correspond in special technical feature, since the products per se and the effects produced in the methods of treatment are unrelated to the special technical feature of the properties of the specific strains of the deposited microorganisms per se.

No common inventive concept is shared among groups V and III since the composition as claimed is not required to obtain equol, for example. Compositions comprising equol lack novelty and may be obtained from mare's or human urine. See, e.g., Merck Index, page 618; or can be prepared microbially. See, e.g., Chang *et al.*, page 1892, bridging paragraph between col. 1 and col. 2.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of Group I would not necessarily anticipate or make obvious the other groups.

For these reasons restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

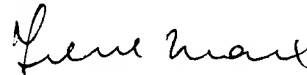
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx
Primary Examiner
Art Unit 1651